

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-27 are pending in the application, with 1 and 23 being the independent claims. Claim 23-27 have been allowed. Claims 1-5 and 11-17 have been amended.

Support for the amendment to claim 1 may be found throughout the specification as filed including, *inter alia*, the examples.¹ The amendments to claims 2-5 and 11-17 were made to remove recitation of the word "step".

These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-8 and 10-22 for allegedly being unpatentable over International Published Application WO 02/00844 (Evans) in view of U.S. Patent 5,811,088 (Hunter) under 35 U.S.C. § 103(a). Applicants respectfully traverse this rejection as it may apply to the currently pending claims.

¹ Applicants note that negative limitations need not be present *in haec verba* in the specification to be fully supported. *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976). See also *In re Johnson*, 588 F.2d 1008, 1017 (C.C.P.A. 1977).

The Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the cited art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). To accomplish this, the Examiner must provide both a suggestion or motivation to combine the art and a reasonable expectation of obtaining the claimed invention based upon that combination of art. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). A *prima facie* case of obviousness requires, *inter alia*, that all claimed limitations must be taught or suggested by the prior art. *In re Royka*, 490 180 USPQ 580 (CCPA 1974). Applicants assert that the cited references do not teach or suggest all the limitations of the currently pending claims.

Solely in an effort to advance prosecution, and not acquiescing in the propriety of the Examiner's rejection, Applicants have amended claim 1 to recite "wherein said mixing step does not require vortexing." As stated in the application, "the method described in WO 02/00844, requires vortexing of all components and multiple cycles of cooling and heating to achieve [sic] a particle size in the range of 200-500 nm." Page 13, para. [0059]. Evans describes the preparation of CRL-1005 formulations containing DNA and BAK as follows: "[a]fter the addition of BAK the formulation was vortexed *extensively*, while the temperature was allowed to increase from ~2°C to above the cloud point." Page 32, ll. 33 - page 33, ll. 2 (*emphasis added*). Indeed, the method taught in Evans requires vortexing after every thermal cycle. One of ordinary skill in the art, upon reading Evans would conclude that vortexing was required to achieve the desired particles. There is no suggestion in Evans of any other technique. Thus, Applicants discovery that vortexing is not required was surprising and provides significant

advantages over Evans. For example, it is well known that polynucleotide molecules may undergo undesirable fragmentation with vortexing. As such, the currently claimed methods are not taught or suggested by the combination of Evans in view of Hunter. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

The Examiner has also rejected claim 9 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Evans and Hunter as applied to claims 1-8 and 11-22 above, and further in view of U.S. Patent 6,933,286 (Emanuele). Applicants respectfully traverse this rejection.

As stated *supra*, Evans and Hunter do not teach all elements of the currently pending claims. Emanuele does not cure the deficiencies of Evans and Hunter because the combined cited references still do not teach or suggest the production of cationic, block copolymers and polynucleotide compositions without the need for vortexing. As such, Applicants respectfully assert that a *prima facie* case of obviousness has not been established and respectfully request that the Examiner reconsider and withdraw the rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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